

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION and
EXPANDABLE GRAFTS PARTNERSHIP,

Plaintiffs,

v.

ADVANCED CARDIOVASCULAR SYSTEMS,
INC., GUIDANT CORPORATION, ARTERIAL
VASCULAR ENGINEERING, INC., BOSTON
SCIENTIFIC CORPORATION, and SCIMED
LIFE SYSTEMS, INC.,

Defendants.

CASE NO. 97-550-SLR

**SECOND AMENDED COMPLAINT
AND DEMAND FOR JURY TRIAL**

Plaintiffs Cordis Corporation ("Cordis") and Expandable Grafts Partnership ("EGP"), for a second amended complaint against defendants Advanced Cardiovascular Systems, Inc., Guidant Corporation, Arterial Vascular Engineering, Inc., Boston Scientific Corporation, and Scimed Life Systems, Inc., allege as follows:

JURISDICTION AND VENUE

1. Plaintiff Cordis is a corporation organized and existing under the laws of the State of Florida and having principal places of business at 40 Technology Drive, Warren, New Jersey and at 14201 N.W. 60th Avenue, Miami Lakes, Florida.

2. Plaintiff EGP is a partnership organized and existing under the laws of the State of Texas and having an address at 1500 NationsBank Plaza, 300 Convent Street, San Antonio, Texas 78230.

3. Upon information and belief, Advanced Cardiovascular Systems, Inc. ("ACS") is a corporation organized and existing under the laws of the State of California and having its principal place of business in California. ACS is doing business in this district in that it offers products for sale in this district, including, but not limited to, the infringing product at issue in this case.

4. Upon information and belief, Guidant Corporation ("Guidant") is a corporation organized and existing under the laws of the State of Indiana and, on its own and through its control of Advanced Cardiovascular Systems, Inc., conducts business in this judicial district, including, offering the infringing product for sale within this district.

5. Upon information and belief, Arterial Vascular Engineering, Inc. ("AVE") is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in California. Upon information and belief, AVE regularly does or solicits business in the State of Delaware, engages in a persistent course of conduct in the State of Delaware, or derives substantial revenue from services or things used in the State of Delaware, including offering the infringing product for sale within the district.

6. Upon information and belief, Boston Scientific Corporation ("BSC") is a corporation organized and existing under the laws of the State of Delaware and

having its principal place of business in Massachusetts. Upon information and belief, BSC regularly does or solicits business in the State of Delaware, engages in a persistent course of conduct in the State of Delaware, or derives substantial revenue from services or things used in the State of Delaware.

7. Upon information and belief, Scimed Life Systems, Inc. ("Scimed") is a corporation organized and existing under the laws of the State of Minnesota and having a principal place of business in Minnesota. Scimed is a wholly owned subsidiary of BSC. Upon information and belief, Scimed regularly does or solicits business in the State of Delaware, engages in a persistent course of conduct in the State of Delaware, or derives substantial revenue from services or things used in the State of Delaware.

8. This action arises under the patent laws of the United States, Title 35, United States Code, and the Federal Declaratory Judgment Act, 28 U.S.C. § 2201. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c) and § 1400.

AS AND FOR A FIRST CAUSE OF ACTION

(Patent Infringement)

10. Plaintiffs Cordis and EGP repeat and reallege each and every allegation of paragraphs 1 through 9 above as though fully set forth herein.

11. United States Letters Patent No. 4,733,762, entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable

Intraluminal Graft"("the '762 patent") issued on April 26, 1988. A true and correct copy of the '762 patent is attached as Exhibit A.

12. United States Letters Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft" ("the '417 patent") issued on April 7, 1992. A true and correct copy of the '417 patent is attached as Exhibit B.

13. United States Letters Patent No. 5,195,984 entitled "Expandable Intraluminal Graft" ("the '984 patent") issued on March 23, 1993. A true and correct copy of the '984 patent is attached as Exhibit C.

14. EGP holds title to the '762, '417 and '984 patents. Cordis is the exclusive licensee of the '762, '417 and '984 patents.

15. The statutory notice requirements have been given for all licensed stents manufactured and sold under the '762, '417, and '984 patents.

16. ACS and Guidant are infringing the '762 and '417 patents by making, using, offering for sale, and/or selling within the United States and/or importing into the United States stents for implantation in human vessels and arteries as claimed in the '762 and '417 patents, and/or are inducing or contributing to such infringement in violation of 35 U.S.C. § 271.

17. AVE is infringing the '762, '417 and '984 patents by making, using, offering for sale, and/or selling within the United States and/or importing into the United States stents for implantation in human vessels and arteries as claimed in the '762, '417

and '984 patents, and/or is inducing or contributing to such infringement in violation of 35 U.S.C. § 271

18. Upon information and belief, BSC and Scimed are infringing the '762 and '417 patents by importing into the United States stents for implantation in human vessels as claimed in the '762 and '417 patents in violation of 35 U.S.C. § 271. Upon information and belief, those acts have not been solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. Upon information and belief, BSC and Scimed intend upon receipt of regulatory approvals to begin making, using, offering for sale and selling within the United States and/or importing into the United States stents for implantation in human vessels as claimed in the '762 and '417 patents in violation of 35 U.S.C. § 271.

19. Cordis and EGP have been, and continue to be, damaged by all defendants' infringement of the '762 and '417 patents and by AVE's infringement of the '984 patent.

20. Upon information and belief, ACS, Guidant and AVE have willfully infringed the '762 and '417 patents, and AVE has willfully infringed the '984 patent.

AS AND FOR A SECOND CAUSE OF ACTION

(Declaratory Judgment Action)

21. Plaintiffs Cordis and EGP repeat and reallege each and every allegation of paragraphs 1 through 20 above as though fully set forth herein.

22. Upon information and belief, BSC and Scimed have taken substantial steps in preparation to enter the United States stent market with its NIR stent, including, but not limited to, stockpiling NIR stents in the United States for distribution in the United States upon FDA approval.

23. BSC and Scimed filed an action for a declaratory judgment, captioned Boston Scientific Corporation et al. v. Johnson & Johnson et al., Civ. 97-11381WGY (D. Mass.) (the "Massachusetts action"), asserting that United States Letters Patent No. 4,733,665 and the '417 patent are invalid, unenforceable and not infringed. In that action, BSC and Scimed have asserted that they have "taken substantial steps in preparation to enter the United States market for intraluminal balloon expandable stents with the NIR stent." On October 14, 1997, the District Court denied defendants' motion to dismiss the Massachusetts action for lack of a case or controversy. The Massachusetts action recently was transferred to the District of Delaware and has been assigned C.A. No. 98-19-SLR.

24. Upon information and belief, BSC and Scimed have filed a 510(k) application with the FDA seeking approval to market the NIR stent for use in biliary indications. BSC stated in its complaint in the Massachusetts action that it expected approval to market the NIR stent for biliary indications by late fall of 1997.

25. Upon information and belief, on January 28, 1998 BSC and Scimed filed a Pre-Market Approval application with the FDA seeking approval to market the NIR stent for use in coronary indications and expect quick approval.

26. Those activities have placed Cordis under a reasonable apprehension that BSC and Scimed will infringe the '762 and '417 patents. There now exists a justiciable case and controversy for adjudication by the Court.

WHEREFORE, plaintiffs Cordis Corporation ("Cordis") and Expandable Grafts Partnership ("EGP") demand judgment against Advanced Cardiovascular Systems, Inc. ("ACS"), Guidant Corporation ("Guidant"), Arterial Vascular Engineering, Inc. ("AVE"), Boston Scientific Corporation ("BSC"), and Scimed Life Systems, Inc. ("Scimed") for:

- a. An order and decree that defendants ACS and Guidant have infringed United States Letters Patent No. 4,739,762 ("the '762 patent") and United States Letters Patent No. 5,102,417 ("the '417 patent");
- b. An injunction prohibiting ACS and Guidant from infringing the '762 and '417 patents;
- c. An order and decree that defendant AVE has infringed the '762 patent, the '417 patent and United States Letters Patent No. 5,195,984 ("the '984 patent");
- d. An injunction prohibiting AVE from infringing the '762, '417, and '984 patents;
- e. An order and decree that defendants BSC and Scimed have infringed the '762 and '417 patents;
- f. A declaration that the manufacture and sale of the NIR stent by BSC and Scimed infringes the '762 and '417 patents;

- g. An injunction prohibiting BSC and Scimed from infringing the '762 and '417 patents;
- h. An award of damages adequate to compensate Cordis and EGP for infringement of the '762, '417 and '984 patents;
- i. An order adjudging and decreeing that ACS, Guidant and AVE have willfully infringed the '762 and '417 patents and that AVE has willfully infringed the '984 patent;
- j. An award of attorneys' fees and costs of suit; and
- k. Such other and further relief as this Court deems just and appropriate.

JURY DEMAND

Plaintiffs Cordis and EGP hereby demand trial by jury on all issues triable
to a jury.

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45988.